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09/728,207	12/01/2000	Yoshiyuki Nagai	50026/005002	4421

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EXAMINER
MOSHER, MARY

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1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/728,207	Applicant(s) Nagai et al
	Examiner Mary Mosher	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *21/1/00, 3/26/01, 4/23/01* .

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. *09/071,591* .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4, 5, 6*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 11-12, 14 of copending Application No. 09/132,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus expressing chemokines and methods of use overlap in scope with the broadly claimed recombinant Sendai virus and methods of use claimed in this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-11 of copending Application No. 09/436,504. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the claims overlap in scope, such that the copending claims to methods of producing chemokines using Sendai virus and virus-infected eggs overlap in scope with the broadly claimed recombinant Sendai virus products and methods of use claimed in this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 09/702,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant replicative Sendai virus is an obvious species within the scope of the claimed copending paramyxoviruses with foreign genes inserted in intergenic regions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/823,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with HIV DNA and methods of use overlap in scope with the broadly claimed recombinant Sendai virus and methods of use claimed in this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "having a desired foreign gene inserted, or a desired gene deleted or inactivated..." Reading the claims in light of the specification, the intended scope of "a foreign gene" is not clear, and it is also not clear whether or not "a desired foreign gene inserted, or a desired gene deleted or inactivated" includes or excludes modifications such as replacement of part of a Sendai gene without fully deleting or inactivating the Sendai gene. For example, Kato et al teaches replacement of part of the F gene with sequence from a distinct Sendai isolate. ON the one hand, the F sequence is foreign to the original isolate, and it is inserted into the Sendai genome (with deletion of the corresponding original sequence). On the other hand, the foreign material is not an entire gene, and it is substituted, not simply inserted. Is this "having a foreign gene inserted, or a desired gene deleted"? This affects all of the dependent claims.

Claims 7 and 8 are also unclear. As discussed in the prosecution of parent application 09/071,591, it is not clear what constitutes "a protein of an equivalent activity to said NP, P, or L proteins". These proteins have many activities, and it is not clear what is required, or where one would find proteins of "an equivalent activity".

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a "disseminative" virus with a foreign gene insertion before the NP ORF, does not reasonably provide enablement for the full scope of "disseminative" viruses with inserts at any genome location, or with Sendai genes deleted or inactivated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The recitation "retaining the disseminative capability" is understood to be synonymous with "non-defective", meaning that the virus can undergo multiple successive rounds of infection without provision of any helper functions in *trans* (after a one-time reconstitution of infective virus particles in a host cell providing NP, P, and L proteins).

The specification does not teach which genes, if any, in the Sendai virus genome can be deleted or inactivated without rendering the virus defective. Since the Sendai virus genome is small (compared to, say, herpes or pox viruses), one skilled in the art would reasonably expect all of the virus genes to be essential for viral propagation. The specification teaches only one site, upstream of the NP ORF, which is capable of accommodating foreign DNA without rendering the virus defective. Since insertion of a foreign gene can negatively affect the expression of adjacent or downstream virus genes, one skilled in the art is unable to predict the effects of insertion at a different location in the virus genome. Applicant argues that only routine experimentation would be required, considering the state of the art for viral vectors. However, Sendai virus is not closely related to previously engineered viruses (see e.g. applicant's specification, the passage spanning

pages 6-7). Therefore the state of the art for other viral vectors is of limited use to one skilled in the art seeking to engineer Sendai virus. Considering the complete lack of guidance in the specification as to which Sendai virus genes (if any) can be deleted or inactivated without destroying "disseminative capability", and considering that the guidance as to sites permitting insertion while retaining "disseminative capability" is limited to one single site in the virus genome, it is concluded that undue experimentation would be required to enable the full scope of the invention, as claimed.

Claims 7 and 8 are additionally rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for kits and methods involving Sendai NP, P (or P/C), and L proteins , does not reasonably provide enablement for "a protein of equivalent activity". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification provides no guidance to one seeking proteins of activity "equivalent" to the Sendai virus proteins required to reconstitute infectious virus particles. Considering the lack of guidance in the specification and the differences between Sendai virus and previously engineered viruses, it is concluded that enablement is limited to the Sendai proteins.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon a PCT application filed October 22, 1996. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was

filed more than twelve months thereafter. However, in the interest of compact prosecution, this application has been treated as if it made a claim under 35 USC §120 to copending application PCT/JP96/03069, which designated the United States. The Priority Information inserted at the beginning of the specification should be amended to contain the *specific* reference (as continuation or continuation-in-part) relating the first U.S. application to the PCT application.

Certified copies of both the PCT application and the earlier JP priority document were filed in 09/071,591. Because these applications are not in the English Language, applicant cannot rely upon the foreign priority papers to overcome an intervening art rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al (Genes to Cells 1:569-579, 1996). See pages 573-574.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conzelmann 6,033,886. Conzelmann broadly claims a recombinant infectious, replicating paramyxovirus comprising an insertion in an open reading frame, pseudogene, or intergenic region, see claims 1 and 9. Conzelmann does not specifically claim Sendai virus, or recite "disseminative capacity" in the claims. However, Conzelmann does identify Sendai as a paramyxovirus, see column 1, line 21. Conzelmann also provides working examples of "disseminative" recombinant viruses for a different negative-stranded RNA virus, see e.g. Examples 4 and 5. Therefore, it would have been within the ordinary skill of the art to choose Sendai as an obvious species within the scope of the claimed paramyxoviruses, and to produce "disseminative" virus analogous to the specific examples provided in the specification. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 23, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600